

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION**

ALLERGAN SALES, LLC, <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	Civil Action: 1:18-CV-227
vs.)	(Judge Keeley)
)	
TEVA PHARMACEUTICALS USA, INC., <i>et al.</i> ,)	
)	
Defendants.)	
_____)	
)	
FOREST LABORATORIES HOLDINGS, LTD., <i>et</i>)	
<i>al.</i> ,)	
)	
Plaintiffs,)	
)	
vs.)	
)	
MYLAN PHARMACEUTICALS INC.,)	
)	
Defendant.)	
)	

STIPULATION AND ORDER

The Court, upon the consent and request of Plaintiffs Allergan Sales, LLC, Forest Laboratories Holdings, Ltd., Allergan USA, Inc., and Ironwood Pharmaceuticals, Inc. (collectively, "Plaintiffs") and Defendant Mylan Pharmaceuticals Inc. ("Mylan"), hereby acknowledges the following Stipulation and issues the following Order in the above-captioned consolidated cases.

STIPULATION

1. On December 19, 2018, these patent infringement actions (the “Actions”) were transferred from the U.S. District Court for the District of Delaware (C.A. Nos. 16-1114-RGA, 17-1728-RGA, and 18-482-RGA) to this Court (D.I. 272 in 18-226-IMK and D.I. 11 in 18-227-IMG).

2. This Court has subject matter jurisdiction over these Actions and personal jurisdiction over Plaintiffs and Mylan for purposes of the Actions. Solely for purposes of resolving the Actions, Mylan and Plaintiffs have consented to venue in this Court.

3. In the Actions, Plaintiffs have asserted claims against Mylan for infringement of: (a) U.S. Patent Nos. 7,304,036 ("the '036 patent"), 7,371,727 ("the '727 patent"), 7,704,947 ("the '947 patent"), 7,745,409 ("the '409 patent"), 8,080,526 ("the '526 patent"), 8,110,553 ("the '553 patent"), 8,748,573 ("the '573 patent"), and 8,802,628 ("the '628 patent") in connection with Mylan's submission of Abbreviated New Drug Application ("ANDA") 209564 directed to a generic linaclotide (145 mcg and 290 mcg) capsule products to the U.S. Food and Drug Administration ("FDA"); and (b) the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, the '553 patent and the '628 patent in connection with Mylan's submission of ANDA 211381 directed to a generic linaclotide (72 mcg) capsule product to the FDA.

4. Mylan has denied Plaintiffs' claims, raised defenses, and asserted counterclaims. To date, no decision has been obtained from this Court regarding Plaintiffs' claims of infringement or Mylan's defenses or counterclaims.

5. Mylan admits that the submission of ANDA 209564 to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use, and/or

sale of the generic linaclotide (145 and 290 mcg) capsule products described in that ANDA within the United States before the expiration of the asserted patents was a technical act of infringement of each of those patents under 35 U.S.C. § 271(e)(2)(A). This admission is without prejudice to any claim, defense, or counterclaim in any possible future action between Mylan and any of the Plaintiffs regarding any of the asserted patents and any generic product other than the generic products described in ANDA 209564 or ANDA 211381.

6. Mylan admits that the submission of ANDA 211381 to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use, and/or sale of the generic linaclotide (72 mcg) capsule product described in that ANDA within the United States before the expiration of the asserted patents was a technical act of infringement of each of those patents under 35 U.S.C. § 271(e)(2)(A). This admission is without prejudice to any claim, defense, or counterclaim in any possible future action between Mylan and any of the Plaintiffs regarding any of the asserted patents and any generic product other than the generic products described in ANDA 211381.

7. The parties agree that all other claims, defenses, and counterclaims asserted against each other in Plaintiffs' and Mylan's pleadings in the Actions, including the allegations and averments contained therein, should be dismissed, without prejudice.

ORDER

Accordingly, pursuant to the above Stipulation, and upon the consent and request of Plaintiffs and Mylan, **IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:**

1. The filing of ANDA 209564 was a technical act of infringement of each of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, the '553 patent,

the '573 patent, and the '628 patent under 35 U.S.C. § 271(e)(2)(A). No decision of the Court has been obtained by either party regarding whether any making, using, selling, or offering to sell within the United States, or importing into the United States, of the generic linaclotide (145 and 290 mcg) capsule products described by ANDA 209564 would infringe any of those patents.

2. The filing of ANDA 211381 was a technical act of infringement of each of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, the '553 patent, and the '628 patent under 35 U.S.C. § 271(e)(2)(A). No decision of the Court has been obtained by either party regarding whether any making, using, selling, or offering to sell within the United States, or importing into the United States, of the generic linaclotide (72 mcg) capsule product described by ANDA 211381 would infringe any of those patents.

3. All other claims, defenses, and counterclaims asserted by the parties against each other in Plaintiffs' and Mylan's pleadings in the Actions, including the allegations and averments contained therein, are hereby dismissed, without prejudice.

4. Mylan, its officers, agents, servants, employees, and attorneys, and all other persons in active concert or participation with any of them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, any of the generic linaclotide (145 or 290 mcg) capsule products described by ANDA 209564 during the life of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, the '553 patent, the '573 patent, and the '628 patent, including any extensions and pediatric exclusivities, absent a license agreement or other authorization by Plaintiffs, unless all of the claims of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, the '553 patent, the '573 patent

and the '628 patent are found invalid or unenforceable by a court decision from which no appeal has been or can be taken, other than a petition for a writ of certiorari to the U.S. Supreme Court.

5. Mylan, its officers, agents, servants, employees, and attorneys, and all other persons in active concert or participation with any of them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, any of the generic linacotide (72 mcg) capsule product described by ANDA 211381 during the life of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, the '553 patent, and the '628 patent, including any extensions and pediatric exclusivities, absent a license agreement or other authorization by Plaintiffs, unless all of the claims of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, the '553 patent, and the '628 patent are found invalid or unenforceable by a court decision from which no appeal has been or can be taken, other than a petition for a writ of certiorari to the U.S. Supreme Court.

6. Plaintiffs and Mylan each expressly waive any right to appeal or otherwise move for relief from this Stipulation And Order.

7. This Court retains jurisdiction over Plaintiffs and Mylan for purposes of enforcing this Stipulation And Order.

8. This Stipulation And Order shall finally resolve the Actions.

9. This Stipulation And Order is without prejudice to any claim, defense, or counterclaim in any possible future action between Mylan and any of the Plaintiffs regarding any of the patents asserted in the Actions and any generic product other than the generic products described in ANDA 209564 or ANDA 211381.

10. The Clerk of the Court is directed to enter this Stipulation And Order forthwith in all of the Actions.

It is so **ORDERED**.

Respectfully submitted this 24th day of December 2018.

/s/ James F. Companion

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SO ORDERED this 27th day of December, 2018



HONORABLE IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE